

DRAFT/UNAPPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

December 11, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15AM

PRESIDING: Ryan K. Logan, Chairman

MEMBERS PRESENT: Jody Allen
Melvin L. Boone, Sr.
Freedra Cathcart
Michael I. Elliott
Sheila K. W. Elliott
Rafael Saenz
Ellen B. Shinaberry
Cynthia Warriner

MEMBERS ABSENT: Rebecca Thornbury

STAFF PRESENT: Caroline D. Juran, Executive Director
Sammy Johnson, Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
David E. Brown, Director, DHP
Lisa Hahn, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Sylvia Tamayo-Suijk, Executive Assistant

QUORUM: With nine members present, a quorum was established.

APPROVAL OF AGENDA: **The Board voted unanimously to approve the agenda as presented. (motion by Warriner, second by Shinaberry)**

APPROVAL OF MINUTES: The following minutes were considered for approval:

- September 14, 2017, Special Conference Committee
- September 26, 2017, Full Board Meeting
- September 26, 2017, Public Hearing for Scheduling Certain Chemicals
- September 26, 2017, Public Hearing for Dispensing Schedule VI drugs in excess of quantity prescribed and use of automated devices
- September 26, 2017, Formal Hearings
- September 27, 2017, Inspection Special Conference Committee
- October 2, 2017, Telephone Conference Call
- October 10, 2017, Special Conference Committee

- November 2, 2017, Regulation Committee
- November 2, 2017, Formal Hearings
- November 7, 2017, Special Conference Committee

MOTION:

The Board voted unanimously to adopt the minutes from September 14, 2017 through November 7, 2017 as presented, excluding the September 26, 2017, Full Board Meeting. (motion by M. Elliott, second by Saenz)

Prior to adjournment of the Full Board Meeting, the September 26, 2017, Full Board Meeting minutes were reviewed.

MOTION:

The Board voted unanimously to adopt the minutes of the September 26, 2017 Full Board Meeting as amended:

- **Page 1 - Strike the arrival times for Michael Elliott and Cynthia Warriner**
- **Page 5, for the following motions, change “motion by Warriner” to “a motion was offered”:**
 - **The Board voted seven to three to approve the ad hoc committee’s recommendation that no action be taken to mandate temperature monitoring devices, but that the Board develop guidance for pharmacies that highlights the importance for using appropriate packaging materials when delivering temperature-sensitive drugs, to include temperature monitoring devices, if warranted.**
 - **The Board voted eight to two to adopt the ad hoc committee’s recommendation on enforcement of USP Chapter <800> as amended which reads “inspectors begin commenting on deficiencies as of July 1, 2018, and impose no monetary sanctions. Beginning January 1, 2019, monetary sanctions (to be established at a later date) should be imposed for non-compliance with the non-physical standards of chapter <800>, e.g., list of hazardous drugs received or stored in the pharmacy, performance of assessment of risk, etc. Beginning July 1, 2019, monetary sanctions (to be established at a later date) should be imposed for the physical and engineering standards of Chapter <800>.**

(motion by Boone, second by Allen)

PUBLIC COMMENTS:

Mark Johnston, former Executive Director of the Idaho Board of Pharmacy and currently representing CVS Health and District 7 on the NABP Executive Committee, offered support to the petition for rulemaking submitted by CVS for an amendment of Regulation 18VAC110-20-275(B)(2)(d) which pertains to the delivery of dispensed prescriptions to another pharmacy. He commented that he was not aware of any other state requiring the identity of a second pharmacy on the label. CVS proposes using a unique identifier to identify both pharmacies

except when the receiving pharmacy is simply holding the dispensed prescription for pick-up or further delivery and has not been involved in the dispensing functions. He stated that a second pharmacy name on the label creates confusion for the patient as to which pharmacy is best positioned to answer patient questions. In addition, including a second pharmacy name and address on the label encroaches on critical label information and is not an important element in reducing medication errors.

Mr. Johnston offered comment in support of a possible requirement for notification during white bagging/brown bagging processes. CVS only allows brown bagging, never white bagging. Mr. Johnston recommended the Board wait on its deliberations until February 2018 in order to receive model language that NABP may be considering on the subject.

John Lubkowski, Director of Pharmacy, Augusta Health Care, Inc., encouraged the Board to pursue a NOIRA regarding white bagging/brown bagging. He stated concerns with patient access and safety and is looking for guidance from the Board on how to handle the issue.

Michael Thomas, McGuire Woods Consulting, LLC, representing Temp Time, provided oral and written comment regarding draft Guidance Document 110- related to proper delivery of temperature-sensitive drugs. Mr. Thomas requested adding the definition for “chemical degradation” in the guidance document since it is not defined in the Code of Virginia which uses the term in §54.1-3420.2, related to the delivery of drugs by mail, common carrier, or delivery services. In addition, Mr. Thomas requested that the guidance document include language which provides a method for the patient to have knowledge if a temperature variation occurred. This would encourage the patient to have a meaningful conversation with their health care provider regarding the safety and effectiveness of the drug.

DIRECTOR’S REPORT:

Dr. David Brown, Director of the Department of Health Professions, shared that Bill Hazel, Secretary of Health and Human Resources, will not be seeking reappointment. Dr. Brown thanked the opioid workgroup charged with developing core competencies for professional schools to educate students regarding the prescribing and dispensing of opioids. A set of core competencies was developed and in Spring 2018, a steering group will discuss how they will be incorporated in schools of higher education. Dr. Brown informed the Board that Lisa Hahn is now the Chief Operations Officer of DHP. With every change of administration, the top two at-will leadership positions may be occupied by individuals who are largely unfamiliar with agency operations, issues, procedures, and policies. This new position, which is not appointed, was designed to provide the Director and Chief Deputy with an understanding of the entire agency, and to advise and support them.

REGULATORY ACTIONS:

- Legislative Update On

Ms. Yeatts reviewed the list of legislative proposals included in the

2018 General Assembly:

agenda packet and highlighted the three items related to pharmacy:

- Requirement to report the dispensing of Schedule V drugs, for which a prescription has been written, and naloxone to the Prescription Monitoring Program.
- Registration of nonresident warehouse and nonresident third-party logistics providers.
- Creating a fentanyl classification in Schedule I of the Drug Control Act.

Ms. Yeatts reviewed the two bills introduced by Lionell Spruill for an individual whose dispensed drugs are lost, destroyed, or otherwise rendered unusable as a consequence of a natural or man-made disaster that displaces the person from his residence:

- SB 23 Health insurance; coverage for limited drug refills.
- SB 25 Drug Control Act; dispensing drugs without a prescription.

- Regulatory Update:

Ms. Yeatts reviewed the chart of regulatory actions provided in the agenda packet and gave updates on the status. The comment period for the NOIRA for requirement for applicants and licensees to have an e-profile ID closes 12/13/17. Certain chemicals will be added to Schedule I effective 12/13/17.

- Adoption of exempt regulation to add certain chemicals to Schedule I

There was a Public Hearing conducted a 9:12 a.m. this morning pursuant to the requirements of §54.1-3443 of the Drug Control Act.

MOTION:

The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 as presented which places the following chemicals into Schedule I:

Classified as research chemicals:

- 2-(methylamino)-2-phenyl-cyclohexanone (other name: Deschloroketamine)
- 2-methyl-1-(4-(methylthio)phenyl)-2-morpholinopropiophenone (other name: MMMP)
- alpha-ethylaminohexanophenone (other name: N-ethylhexedrone)
- N-ethyl-1-(3-methoxyphenyl)cyclohexylamine (other name: 3-methoxy-PCE),
- 4-fluoro-alpha-pyrrolidinohexiophenone (other name: 4-fluoro-alpha-PHP),
- N-ethyl-1,2-diphenylethylamine (other name: Ephenidine)

Classified as powerful synthetic opioids:

- N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole fentanyl),
- 3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900),
- 2-(2,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-

methylacetamide (other name: U-48800)

Classified as central nervous system stimulants:

- **Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (4-fluoromethylphenidate),**
- **Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate)**

(motion by Warriner, second by Cathcart)

- Adoption of final regulation on refills of CVI and emergency kits/stat boxes; addition of naloxone

Ms. Yeatts provided a brief background of the proposed regulations. Ms. Juran suggested that the proposed language in 18VAC110-20-320(B) be amended to expand the allowance to include the dispensing of new prescriptions as well and not be limited to refills. Ms. Allen provided comment that the title of the regulation should be amended to make it easier to find the regulation. Ms. Warriner agreed.

MOTION:

The Board voted unanimously to amend:

- **the title of 18VAC110-20-320 to read “Dispensing or refilling of Schedules III through VI prescriptions”;**
- **the proposed language in 18VAC110-20-320(B) to read “Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for drugs of concern as defined in §54.1-2519 of the Code of Virginia, a pharmacist, using professional judgement and upon request by the patient, may dispense or refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration”; and,**
- **the proposed language of 18VAC110-20-540(A)(2) by deleting the word “and” prior to “diazepam rectal gel” and inserting “, and the intranasal spray formulation of naloxone” prior to the words “may be included.” (motion by Allen, second by Warriner)**

MOTION:

The Board voted unanimously to adopt as a final action the proposed amendments to Regulations 18VAC110-20-320 and 18VAC110-20-540, both as amended, and 18VAC110-20-550 and 18VAC110-20-555, as presented. (motion by Warriner, second by Boone)

- Adoption of two changes to proposed regulations (Periodic Review) relating to kickbacks & definition of electronic prescription

Ms. Yeatts reported that the changes to amendments to 18VAC110-20-390 and 18VAC110-21-45 relating to kickbacks, are necessary due to the proposed splitting of current Chapter 20 into Chapter 20 (facilities) and Chapter 21(individuals). In Chapter 20 the word “pharmacist” will be amended to “pharmacy” and in both chapters the phrase “unless fully disclosed in writing to the patients and any third party payor” will be eliminated.

Ms. Yeatts also reported that counsel recently informed her that amending the definition of electronic prescriptions to conform to 2017 legislation may not be an exempt action since the effective date of the legislation

was delayed until 2020. Rather than starting with another regulatory action, staff recommends adding the amendment to the periodic regulatory review action.

MOTION:

The Board voted unanimously to adopt:

- **An amendment of 18VAC110-20-390 to read, “A. A ~~pharmacist-pharmacy~~ shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, "kickbacks," fee-splitting, or special charges in exchange for prescription orders ~~unless fully disclosed in writing to the patient and any third party payer.~~ B. A ~~pharmacist-pharmacy~~ shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.;**
- **A new section 18VAC110-21-45 to read, “Kickbacks, fee-splitting, interference with supplier. A. A pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, "kickbacks," fee-splitting, or special charges in exchange for prescription orders ~~unless fully disclosed in writing to the patient and any third party payer.~~ B. A pharmacist shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.**

and to include these adoptions in the current periodic regulatory review action. (motion by Saenz, second by Boone)

MOTION:

The Board voted unanimously to adopt an amendment of the definition of “electronic prescription” in 18VAC110-20-10 as presented and which reads, “means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be transmitted in accordance with 21 CFR Part 1300 ~~and is transmitted to a pharmacy as an electronic data file.~~” and to include this adoption in the current periodic regulatory review action. (motion by Warriner, second by Cathcart)

**PETITION FOR RULE
MAKING:**

- **Amend 18VAC110-20-275, *Delivery of Dispensed Prescriptions***

The Board reviewed a petition for rulemaking submitted by CVS Health to amend Regulation 18VAC110-20-275(B)(2)(d) to allow the prescription label to contain a “unique identifier” to identify all pharmacies involved in filling and dispensing a prescription, in lieu of listing all pharmacies on the label, as is currently required through interpretation. The petition proposes that the unique identifier would not be required to identify a pharmacy solely involved in the holding of a

prescription for pick-up or further delivery when that pharmacy has not shared in other filling or dispensing functions. In addition to a comment from CVS, two other comments were received during the public comment period. The Board briefly discussed the implications of the possible amendment when both pharmacies are involved in the dispensing process as opposed to the receiving pharmacy serving solely as a depot for the patient to pick up the dispensed drug. They also discussed which pharmacy may be the more appropriate pharmacy to answer the patient's questions and therefore, which pharmacy's information should be included on the prescription label. Mr. Johnston stated that if it involved a specialty drug, he believed the specialty pharmacy delivering the dispensed drug to the patient's local CVS pharmacy location would be the better pharmacy to answer the questions. Consensus on this subject was not reached.

MOTION:

The Board voted unanimously to refer the petition for rulemaking to the Regulation Committee for a recommendation on whether or not to adopt a NOIRA. (motion by Saenz, second by S. Elliott)

- Amend Guidance Document 110-1, *Categories of Facility Licensure*

As of July 1, 2017, two new categories of licensure have been added to the document: Nonresident Manufacturer and Third-Party Logistics Provider.

MOTION:

The Board voted unanimously to adopt the amendments to Guidance Document 110-1, *Categories of Facility Licensure*, as presented. (motion by M. Elliott, second by Shinaberry)

- Amend Guidance Document 110-04, *Guide to Continuing Pharmacy Education Requirements*

In addition to edits recommended for clarity, a Question and Answer on counting hours worked as a volunteer at a free clinic or local health department as continuing education has been added.

MOTION:

The Board voted unanimously to adopt the amendments to Guidance Document 110-04, *Guide to Continuing Pharmacy Education Requirements*, as presented. (motion by Allen, second by Warriner)

**REPORT FROM
REGULATION COMMITTEE:**

- Adopt NOIRA to address White Bagging and Brown Bagging

Mr. Elliott provided background from the Regulation Committee meeting regarding adopting regulation to define white bagging, brown bagging, prohibit brown bagging of drugs requiring reconstitution or compounding prior to administration, and setting specific requirements for specialty pharmacies participating in white bagging, which includes notifying the receiving pharmacy of the shipment to ensure appropriate coordination of patient care. The 2016 Pharmacy Benefit Manager Workgroup, a broad stakeholder group, recommended the Board of Pharmacy review the practice of white bagging and brown bagging to address any issues of

concern. The Board identified Regulation 18VAC110-20-275, *Delivery of Dispensed Prescriptions* as a regulation potentially needing amending to address white bagging and brown bagging.

MOTION:

The Board voted unanimously to adopt a NOIRA relating to white bagging and brown bagging to include the following actions:

- **Define white bagging and brown bagging;**
- **Consider regulation of brown bagging of drugs requiring special storage requirements, reconstitution or compounding prior to administration;**
- **Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy of the shipment to ensure appropriate coordination of patient care;**
- **Requiring the pharmacy to provide to the receiving pharmacy an estimated arrival date, the name of the patient to whom the drug has been dispensed, and the exact address where the product has been shipped. (motion by Saenz, second by S. Elliott)**

- Amend Guidance Document 110-36, *Compliance with USP Standards for Compounding*

USP has delayed implementation of Chapter <800> to December 1, 2019. Therefore, the Regulation Committee recommended amendments to paragraph 2 of the guidance document, inclusion of USP's Frequently Asked Questions for Chapter <800>, and inclusion of a link to the National Institute of Occupational Safety and Health (NIOSH) list. The Committee also recommended that the Board begin the education process through inspections (which will not result in disciplinary action prior to the effective date of the chapter) within the next six months.

MOTION:

The Board voted unanimously to amend Guidance Document 110-36, *Compliance with USP Standards for Compounding*, as presented and instruct the inspectors to begin educating licensees within the next six months on areas of non-compliance identified during pharmacy inspections. (motion by S. Elliott, second by Allen)

- Amend Guidance Document 110-23, *Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide*

The Regulation Committee requested staff to cross-walk Guidance Document 110-23 with Guidance Document 110-9 for consistency and current regulations to determine if additional edits were necessary. It also recommended that the words "major" and "minor" be stricken and that Deficiency #13 be eliminated. Mr. Logan suggested that the Board may want to re-evaluate the current pharmacy inspection program, wherein an expedited pre-hearing consent order with monetary sanctions is offered at the conclusion of a routine pharmacy inspection, prior to amending Guidance Document 110-23 and implementing a similar process for the physician selling inspections. Ms. Shinaberry commented that Guidance Document 110-9 has become quite lengthy and should be reviewed. She also questioned whether the inspection process has made pharmacies safer and whether the inspection model has made pharmacists change their practice. Ms. Warriner commented that having repeat offenders indicates that behavior hasn't always been changed by the inspection model. Mr. Johnson provided comment that the inspection program has

grown and a review may be appropriate to ensure the inspections are reviewing for substantial compliance.

MOTION:

The Board voted unanimously to table the amendment of Guidance Document 110-23, *Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency* and to create an Ad Hoc Committee to evaluate the current routine pharmacy inspection program. (motion by M. Elliott, second by Cathcart)

ADOPTION OF GUIDANCE DOCUMENTS:

- Adoption of Guidance Document on Delivering Temperature-Sensitive Drugs

On September 26, 2017, the Board voted seven to three to approve the Ad Hoc Committee's recommendation that no action be taken to mandate temperature monitoring devices, but that the Board develop guidance for pharmacies that highlights the importance for using appropriate packaging materials when delivering temperature-sensitive drugs, to include temperature monitoring devices, if warranted.

MOTION:

A motion was made to adopt the Guidance Document on Delivery of Dispensed Drugs as presented. (motion by Shinaberry, second by S. Elliott)

An amendment to Guidance Document on Delivery of Dispensed Drugs was proposed by Mr. Saenz. The amendment substitutes the word "require" with the word "include" on line 4 of paragraph 2.

MOTION:

The Board voted five to four to amend the Guidance Document on Delivery of Dispensed Drugs by substituting the word "require" with the word "include" in the sentence "The packaging may ~~require~~ include the use of a temperature monitoring device, particularly for drugs that are temperature-sensitive." found in the second paragraph. (motion by Saenz, second by M. Elliott, opposed: Shinaberry, Cathcart, S. Elliott, Warriner)

Ms. Shinaberry withdrew her motion to approve the Guidance Document on Delivery of Dispensed Drugs as amended.

MOTION:

The Board voted seven to one to adopt the Guidance Document on Delivery of Dispensed Drugs, as amended. (motion by Allen, second by Boone; S. Elliott opposed, Cathcart abstained)

- Adoption of Guidance Document on Drug Disposal

On September 26, 2017, the Board voted unanimously to accept the Ad Hoc Committee's recommendation for staff to create a guidance document regarding the disposal of controlled substances.

MOTION:

The Board voted unanimously to adopt the Guidance Document pertaining to Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs, as presented. (motion by M. Elliott, second by Allen)

NEW BUSINESS:

- Request from Gates Healthcare Associates, Inc. regarding cGMP inspections

Ms. Juran provided history of approving outside entities to perform current good manufacturing practices (cGMP) inspections. Ms. Allen asked if other states accept cGMP inspection reports from entities that are not state or federal regulatory agencies. Ms. Juran indicated she is not aware of any other states that accept cGMP inspection reports from entities that are not state or federal regulatory agencies. Mr. Saenz suggested the Board pursue the same process as was done with Bestech, Inc. which involved an in-person presentation to the Board.

ACTION ITEM:

Invite Gates Healthcare to make a presentation to the March 29, 2018 Full Board Meeting, offering materials in advance of the meeting, and be available to answer any related questions.

REPORTS:

- Chairman's Report:
- Report on Board of Health Professions:
- Report on Licensure Program:
- Report on Disciplinary Program:

Mr. Logan stated that he had nothing to report at this time.

Mr. Logan provided an update on the most recent Board of Health Professions (BHP) meeting. Mr. Logan restated Dr. Brown's announcement that Lisa Hahn accepted the new position of Chief Operating Officer. Michelle Schmidt had reported to the BHP that DHP Enforcement received 5,400 complaints last year, of which 75% were completed within 90 days. Complaints may now be submitted online which resulted in an increase in the number of complaints received. Mr. Logan shared that DHP partnered with Virginia Commonwealth University to design its new logo and provided the Board with an example. Information from a presentation to the BHP indicates that job satisfaction and education debt are most associated with delayed retirement.

Mr. Johnson reported the Board currently licenses 38,218 individuals and facilities. The Board issued 1,034 licenses and registrations for the period of September 1, 2017 through November 30, 2017. Inspectors conducted 521 facility inspections including 206 routine inspections of pharmacies: 43 (21%) resulted in no deficiency, 66 (32%) with deficiencies and 97 (47%) with deficiencies and a consent order. Mr. Johnson reviewed the chart providing a graphic display of inspection deficiencies by quarter since September 2012 and reviewed the most frequently cited deficiencies for the reporting period. Mr. Johnson corrected the statistics reported at the December 26, 2017 meeting: 52 (23%) resulted in no deficiency, 100 (43%) with deficiencies and 80 (34%) with deficiencies and a consent order.

Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report as of November 30, 2017. She reviewed the stages of the patient care cases as well as the non-patient care cases. The report indicates that the Board had 282 open cases as of that date with 111 being patient care cases and 171 being non-patient care cases. Further, Ms. Reiniers-Day discussed the Report for the Board's

Second Quarter for the patient care cases as well as the non-patient care cases and each relevant priority. Lastly, the HPMP Monthly Census Report for November 30, 2017 was reviewed.

- Executive Director's Report:

Ms. Juran provided an update on the pharmaceutical processor program. The Board of Pharmacy expects to begin issuing conditional permits in June/July 2018 so that construction of the facilities can begin. The facilities have one year to build and after inspection by DHP, the final permits will be issued. Ms. Juran shared that there has been a 60% increase in licensing over the past 10 years. Ms. Juran also announced that Ellen Shinaberry has accepted the new Deputy Executive Director position for the Board of Pharmacy as of February 10, 2017. This will necessitate her resigning from the Board as a board member at that time.

CONSIDERATION OF SUMMARY SUSPENSION

JASON LAMONT ROSS
Registration No: 0230-011467

James Schliessmann, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a possible summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

MOTION:

Upon a motion by Mr. Saenz, and duly seconded by Ms. Allen, the Board voted 7-0 in favor of the motion that, according to the evidence presented, the continued practice by Jason Lamont Ross as a pharmacy technician poses a substantial danger to the public; and therefore, the registration for Mr. Ross shall be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Mr. Ross for the indefinite suspension of his pharmacy technician registration for not less than two years.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 1:49pm.

Ryan Logan, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE: